UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK	
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HOLLY MARIE HUMMEL, on behalf of herself and others similarly situated,) No. 07-civ-5473
Plaintiff,) PLAINTIFF'S STATEMENT OF) DISPUTED MATERIAL FACTS
-against-))
ASTRAZENECA LP,)
Defendant.)
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PLAINTIFF'S STATEMENT OF DISPUTED MATERIAL FACTS IN OPPSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

Plaintiff Holly Hummel ("Hummel" or "Plaintiff"), pursuant to Local Civil Rule 56.1(b), submits this Statement of Disputed Material Facts in support of her Opposition to Defendant's Motion for Summary Judgment

DISPUTED MATERIAL FACTS

I. ASTRAZENECA IMPROPERLY CLASSIFIED HUMMEL AS EXEMPT

A. BACKGROUND

1. Plaintiff Holly Hummel ("Hummel" or "Plaintiff") is a New York resident and was employed as a Pharmaceutical Sales Specialist ("PSS") by AstraZeneca ("AZ" or "Defendant") from December 1999 through October 2005. Declaration of Holly Hummel ("Hummel Decl.") at \P 1-2.

- 2. District managers are the immediate supervisors for all PSSs. Deposition Transcript of Cindy Atha¹ ("Atha Dep."). at 64:17-22.
- 3. Regional sales directors are the supervisors of district managers. Atha Dep. at 64:23-65:5.

В. ASTRAZENECA CLASSIFIED HUMMEL AS EXEMPT

- 4. PSSs -- including Hummel -- do not receive overtime pay for working more than eight hours per day or 40 hours per week. Hummel Decl. at ¶ 5; Atha Dep. at 226:14-16.
- 5. Defendant has uniformly classified all PSSs -- including Hummel -- as exempt from overtime compensation. Def's Answer to First Am. Compl. ¶ 59; Atha Dep. at 228:19-22.

C. TRAINING PROVIDED TO PLAINTIFF BY DEFENDANT

- 6. Newly hired PSSs participate in initial training that is held at Defendant's headquarters in Wilmington, Delaware and all PSSs receive identical additional training at their respective business centers located throughout the country. Deposition of Debra Ventura ("Ventura Dep."), Defendant's Director of Sales Training, at 55:1-5; 55:9-11.
- 7. Defendant trained Plaintiff and other PSSs on scripts to use when on a sales call with a physician. Def. Tab 1 at 236:25-241:6 ("Then the company says, Here is marketing, this is what you can say. This in on label. This is what you can't say, but here's the script. So if the doctor says, you know, this, typically is an introduction of yourself. And then if the doctor says this, here is a response for that.")

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¹ Unless otherwise indicated, all Exhibits are annexed to the Declaration of Michael DiChiara, submitted herwith.

- 8. PSSs do not need pharmacological training or scientific knowledge to perform their job. AZ provided the PSSs with all the information needed to conduct a sales call. Also, PSSs do not have the authority to communicate with health care providers about the efficacy or indications for AZ products. Hummel Decl. at ¶ 17; Deposition of Susan Johnson ("Johnson Dep."), former PSS, at 29:2-20 (English major, did not need a science or medical background to be a successful PSS); Deposition of Mark Capistrano ("Capistrano Dep."), a District Manager for AZ, at 229-230 (not need science background); Deposition of Stephanie Dempsey ("Dempsey Dep."), a current Regional Alignment Leader and former District Manager for AZ, at 44:16-45:19 (PSSs do not need background in medicine, healthcare, or science).
- 9. Throughout her employment, Hummel received continuing training and evaluations from her district managers who would sometimes accompany Hummel on visits with doctors and provide feedback about the interactions. Hummel Decl. at ¶27-28.
- 10. Upon starting at AZ, Hummel received training on AZ pharmaceutical products as well as training on how to present information about the pharmaceutical products to doctors. Hummel Decl. at ¶ 27.
- 11. Hummel received intensive training in which it was dictated 1) how a PSS was to interact with doctors, 2) the message to give to doctors about AZ products and 3) how to present the message. According to AZ, everything a PSS did was considered "sales," even though PSSs cannot directly sell or take orders for a product. Hummel Decl. at ¶¶10, 16.

D. JOB DUTIES OF PLAINTIFF AND ALL PSSs

- 12. All PSSs -- including Hummel -- are primarily responsible for meeting with an AZ-generated list of physicians within their assigned territory to provide AZapproved information about AZ's pharmaceutical products. Hummel Decl. at ¶ 9, 12; Overview of AstraZeneca Business Policies and Regulatory Review, DiChiara Decl. at Ex. 12, AZB C 0001540-0001541 (outlining requirements for promotional discussions).
- 13. The goal of PSSs --including Hummel --was to keep AZ products in the minds of doctors so that they might consider prescribing AZ products in the future. Hummel Decl. at ¶ 9.
- 14. While in the field, all PSSs must make face-to-face calls on prescribers (i.e. doctors) within their assigned territories. DiChiara Decl., Ex. 10, AZB C0001336-1338.
- "AstraZeneca defines a sales call as a face-to-face discussion between a 15. prescriber and a PSS, where an approved visual aid and/or clinical paper is used to address the needs of the customer, and the most current promotional message is persuasively delivered. All calls must include: product safety information, a direct request from a PSS for the appropriate action from the customer, and an offer to leave the Prescribing Information." Id.
- Defendant, from its Wilmington headquarters, provides each PSS with a list of physicians for them to target with "sales" calls. Ventura Dep. at 123:14-124:15; Hummel Decl. at ¶12.
- 17. Defendant provides PSSs visual aids and clinical papers to be used on sales calls. Ventura Dep. at 103:10-14; 104:4-12; Hummel Decl. at ¶¶ 10, 11.

- 18. Defendant must pre-approve all visual aids and clinical papers. Ventura Dep. at 103:15-18; 104:4-12.
- 19. PSSs spend their time arranging meetings with doctors, gathering AZ-approved materials for meetings with doctors, getting to and from meetings with doctors, providing information to doctors and responding to their questions, and reporting information about their daily work activities through AZ's computer systems. Hummel Decl. at ¶¶ 9, 26; Ventura Dep. at 103:15-18, 104:4-12; DiChiara Decl., Ex. 10 (AZB_C0001336-1338).
- 20. PSSs present information about AZ products from company-generated "detail pieces" that are shown to physicians as part of the product presentation a practice known as "detailing." DiChiara Decl., Ex. 11 (AZB_C0001540 ("Promotions Discussions/Detailing").
- 21. PSSs are prohibited by AZ's policies from providing healthcare providers with gifts or remuneration in exchange for prescriptions of AZ products. DiChiara Decl., Ex. 11, AZB_C 0001539 ("...illegal for anyone (including AstraZeneca) to provide anything of value...to induce or influence that person to prescribe or purchase one of our drugs."); Ex. 16, AZB_C0002637 (illegal to engage in quid pro quo).
- 22. PSSs are not permitted to recommend AZ's products to potential endusers, or obtain a commitment from a physician that she will prescribe an AZ product for a particular patient. DiChiara Decl., Ex. 16, AZB_C 0002650 ("product promotional discussions may not take place with patients); Ex. 16, AZB_C0002657 (a PSS must use "Fair Balance" on promotional calls so that a health care provider can understand benefit to risk ratio of a product to determine is appropriate use); Ex. 17, AZB C0004202

("promotional activities directed towards health care professionals must be designed to help HCP's improve treatment of and services to patients.")

- 23. PSSs do not sell to, interact with, or gather information about AZ's wholesale and retail customers in any way. Bradley Dep. at 22:18-23:2, 40:17-42:9; Hummel Decl. at ¶ 25.
- 24. PSSs educate health care providers and present information to persuade doctors to write prescriptions in order to generate increased demand for AZ products. Ventura Dep. at 52:1-4.
- In executing this informational function, PSSs must comply with numerous AZ policies that constrain what they can say and do during product presentations, whom they must target and how often they must do so, and when they must work. DiChiara Decl., Ex. 17, AZB_C0004202; Ex. 5, AZB_C000820-21; Ex. 6, AZB_C000944; Ex. 7, AZB_C0001020-22; Ex. 8, AZB_C0001222-33; Ex. 9, AZB_C0001238-49; Ex. 10, AZB_C0001336-38; Ex. 11, AZB_C0001538-44; Ex. 12, AZB_C0004230-31; Ex. 13, AZB_C00018072; Ex. 16, AZB_C0002632-73.
- 26. AZ considers the detailing work performed by PSSs to be promotional work. DiChiara Decl., Ex. 16, AZB_C0002636 (purpose of access tools to "promote our products"), AZB_C0002650 ("Product promotional discussions must take placed with HCP's."); Ex. 17, AZB_C0004202; Ex. 15, AZB_C0002632-73; Ventura Dep. 156:17-157:24.

E. WORK HOURS FOR PLAINTIFF AND ALL PSSs

- 27. It is common that PSSs work more than eight hours per day during the work week, do not take meal breaks, and work on the weekends. Hummel Decl. at \P 5. See also Ventura Dep. at 92:21-24.
 - 28. Hummel consistently worked over 40 hours per week. *Id.*
- 29. Hummel worked approximately 10 hours per weekday and also worked on weekends. *Id.*
- 30. On the weekends and when Hummel was not in the field visiting doctors, he worked from home on administrative work, including reading and responding to-emails, speaking with other AZ employees, and preparing reports; he also was sometimes required to travel on the weekends. *Id.* at ¶ 32.

F. HUMMEL'S COMPENSATION

- 31. Hummel, like all PSSs, received a salary and a bonus, which is referred to as the field sales incentive plan ("FSIP"). Ventura Dep. at 373:14-374:1; 428:6-16; 429:16-24; Hummel Decl. at ¶ 6. See also DiChiara Decl., Ex. 14, AZB_C0001820-38.
- 32. The bonus element of Hummel's and all PSSs compensation is based upon an estimate of the number of prescriptions filled in the PSS's territory along with other criteria, including strategic objectives and professional behavior. Hummel Decl. at ¶ 6; Ventura Dep. at 377:4-13; 380:4-381:24; 383:14-19; 384:4-19; 389:18-391:9; 413:5-416:3; 423:15-424:19.
- 33. The bonus was only a small part of Hummel's annual wages. Hummel Decl. at \P \P 6, 34.

- 34. PSSs do not receive "commissions" that salespeople typically receive. PSS's are eligible for the Field Sales Incentive Plan ("FSIP). DiChiara Decl., Ex. 14, AZB_C0001820-38.
- 35. Compensation received according to the FSIP is based on a complicated logarithm which cannot be traced to any individual PSS. DiChiara Decl., Ex. 14, AZB_C0001820-38; Ventura Dep. 377:2-13; Hummel Decl. at ¶ 35.
- 36. Unlike commissions, incentive pay for PSSs in not based solely on sales, as there is a financial component that accounts for 80% of the incentive bonus, but there is also a subjective component of the incentive bonus. DiChiara Decl., Ex. 14, AZB C0001820-38.
- 37. The FSIP is also very unlike a commission because if a PSS is on a performance improvement plan, yet still meets their "sales" target, the PSS is not eligible for a bonus. In addition, if a PSS in on a paid leave of absence and not making sales calls during their leave, the PSS is still eligible for the incentive bonus. DiChiara Decl., Ex. 14, AZB_C0001820-38.
- 38. AZ cannot link the "sale" of a particular drug to particular PSS, because several PSSs will call on the same doctor to promote the same drug. Ventura Dep. at 393:9-395:22 ("But they both would get credit in the calculation of their formula for their bonus...); Capistrano Dep. at 105:5-106:7 (no way to tell which PSS is responsible for increase in market share).
- 39. The link between a PSS's sales calls and a sale is further attenuated because not all pharmacies report their prescription data to IMS, the company that reports

to AZ the number of prescriptions sold. Ventura Dep. at 380:8-381:3, 383:14-389:25 (IMS data is approximately 75% accurate). Bradley Dep. 95:3-22.

- 40. Even Defendant's PSSs had no idea how AZ calculated the bonus aspect of their compensation. Johnson Dep. at 53:11-54:20 (after inquiring how bonus was calculated, did not understand the company's explanation and gave up trying to figure it out).
- 41. PSSs receive credit for prescriptions written by doctors they never called on if the prescription is filled in their territory. Ventura Dep. at 390:13-391:9.

G. ASTRAZENECA MISCLASSIFIED HUMMEL AS AN EXEMPT OUTSIDE SALESPERSON

1. Hummel Did Not Sell Anything Or Take Orders

- 42. Non-PSS employees of AZ are involved in selling and entering into contracts with entities that purchase AZ products. Bradley Dep. at 22:14-23:2; 31:25-33:15; 40:17-42:9; Hummel Decl. at ¶¶19-24.
- 43. PSSs -- including Hummel -- do not sell AZ's products to physicians or to anyone else. *Id*.
- 44. The traditional "sale of cash exchanging and transfer of title taking place does not happen in the sale transaction that occurs with a PSSs and a physician or a health care provider." Ventura Dep. at 242:19-243:5.
- 45. Health care providers do not purchase AZ's products from PSSs. Ventura

 Dep. 372:7-19; Hummel Decl. at ¶ ¶ 20. 23.

- 46. PSSs do not sell samples to health care providers. Ventura Dep. at 167:10-13; 167:20-168:2; 168:15-16; Atha Dep. at 179:16-19.
- 47. PSSs do not negotiate prices or terms for AZ products or services. Hummel Decl. at ¶ 22; Bradley Dep. at 22:14-23:2; 31:25-33:15: 40:17-42:9.
- 48. PSSs do not negotiate or execute contracts for AZ products or services. Hummel Decl. at ¶ 19; Bradley Dep. at 22:14-23:2; 31:25-33:15: 40:17-42:9.
- 49. PSSs do not take orders for AZ products or services. Atha Dep. at 32:15-18; 33:23-34:16.
- 50. Instead, members of the operations group, managed markets, and business development and licensing at AZ receive and process the purchase orders and enter into contracts with the entities that actually purchase AZ products--such as wholesalers, pharmacies, and retailers. Bradley Dep. at 17:14-18:6, 20:25-21:16, 31:25-33-25.
- 51. AZ sells to wholesaler and wholesalers sell to pharmacies. Ventura Dep. at 364:17-19; 366:5-6.
- 52. "Wholesalers buy the AstraZeneca products and consumers purchase through a prescription at the retail level pharmacy the AstraZeneca product. When they do that, it creates the demand for the wholesaler, which then triggers the sale by AstraZeneca." Ventura Dep. at 69:13-19
- 53. Sales to wholesalers account for 90% of all of AZ's sales. Bradley Dep. at 29:8-16 (AZ records income when it ships its product to wholesalers).
- 54. Sales to Medco, a pharmacy benefit manager, account for 8% of AZ's sales. Bradley Dep. at 29:23-30:6 (AZ records income when it ships its product to Medco.)

- 55. The remaining two percent (2%) of AZ's sales is compromised of companies, pharmacies, hospitals, and physicians that purchase Zoladex, an injectable oncology drug, through a third party known as SDS, which takes the orders from physicians. Sales to pharmacies, hospitals, and Zoladex account for less than one-half of one percent of AZ's total sales. Bradley Dep. at 30:7-31:24; 85:18-86:19.
- 56. AZ receives its orders from wholesalers electronically. Bradley Dep. at 37:20-24.
- 57. When AZ ships its products to wholesalers or the other entities that purchase its products, an invoice is generated for which the purchaser must remit payment to AZ, as AZ records income when its product is shipped. Bradley Dep. at 38:16-39:4.
- 58. PSS do not have any role in the order and invoice process. Bradley Dep. at 22:14-23:2; 31:25-33:25; Hummel Decl. at ¶ 25.
- 59. If a hospital wanted to actually purchase an AZ product they would go to a wholesaler who gets it from AZ. Atha Dep. 32:20-33:
- 60. In addition to an invoice being generated when an entity purchases a product directly from AZ, a pick and pack slip is also generated at the warehouse. The pick and pack slip functions as an order form. Bradley Dep. at 50:25-51:25.
- 61. Invoices and pick and pack slips are *not* generated in response to a PSS interacting with a health care provider. The invoices and pick and pack slips are not generated at the time of the PSS's sale call with a health care provider. Nor are they generated following the sales call. The invoices and pick and pack slips are also not

generated when a health care provider writes a prescription for an AZ product or when a patient gets a prescription filled at a pharmacy. Bradley Dep. at 66:6-71:22.

2. **Doctors Do Not Purchase Drugs From PSSs**

- 62. Doctors do not give money to AZ for the purchase of drugs. Atha Dep. at 23:17-20; Hummel Decl. at ¶ ¶ 20. 23.
- The patient or consumer is the one who goes to the pharmacy to purchase 63. and pay for the drug. Atha Dep. at 23:9-16.
- 64. "The health care practitioners don't buy drugs from anyone directly. They don't supply drugs to patients through a prescription." Ventura Dep. at 372:7-10.
- 65. AZ does not record income when a health care provider tells a PSS that he or she will consider prescribing an AZ product. Bradley Dep. at 61:14-21.
- 66. AZ does not record income when a health care provider tells a PSS that he or she will prescribe an AZ product. Id. at 61:23-62:5
- 67. AZ does not record income when a health care provider promises a PSS that he or she will prescribe an AZ product. Id. at 62:7-11.
- 68. AZ does not record income when a health care provider commits to prescribing an AZ product. Id. at 62:14-22.
- AZ does not record income when a health care provider writes a 69. prescription for an AZ product. Id. at 62:24-63:5.
- 70. AZ does not record income when a health care provider gives a prescription to a patient for an AZ product. Id. at 63:7-64:6.
- 71. AZ does not record income when a patient fills a prescription for an AZ product at a pharmacy. Id. at 64:8-13.

- 72. AZ does not record income when a patient pays for a prescription for an AZ product at a pharmacy. *Id.* at 64:15-20.
- 73. AZ does not record income when an insurance company reimburses a pharmacy for a prescription that was filled for an AZ product. Id. at 64:22-65:4.

3. **Non-Binding Commitments From Doctors**

- 74. PSSs ask doctors to perform some action in the future, including prescribe an AZ product to appropriate patients. AZ refers to this as getting a "commitment." Ventura Dep. at 75:7-13; 158:9-15; Hummel Decl. at ¶ 19.
- 75. Doctors do not commit to prescribe a certain number of prescriptions nor do they commit to prescribe a certain drug for a specific patient. Ventura Dep. at 77:8-79:4.
- "The PSS does not get a commitment to purchase." Ventura Dep. at 76. 316:12-13.
- 77. After a PSS receives a "commitment" from a doctor, the doctor is still free to not prescribe the AZ drugs. Atha Dep. at 59:3-29.
- 78. Doctors sometimes give a "commitment" to PSSs but do not subsequent to giving a "commitment" prescribe AZ drugs. Atha Dep. at 59:22-24.
- 79. Hummel did not receive any guarantee from a doctor that the doctor would prescribe the products to patients in the future. Hummel Decl. at ¶ 19

4. PSSs Advertise for AZ

80. AZ invests millions of dollars in print and media advertisement. Atha Dep. at 36:24-37:5; Bradley Dep. at 50:7-12.

- 81. AZ uses advertisements to promote market expansion for its drugs. Pa. Emples. Benefit Trust Fund v. Zeneca, Inc., 499 F.3d 239, 245 (3rd Cir. 2007).
- 82. AZ uses physician-directed pitches by sales representatives as one form of advertisement of its drugs. Pa. Emples. Benefit Trust Fund, 499 F.3d at 245. ("advertisements are published in journals, magazines, and newspapers, and are broadcast through media such as television and radio. Advertisements also come in the form of physician-directed pitches by sales representatives, computer programs, and electronic media.)
- 83. PSSs are part of the "marketing mix" (or "promotional mix") for AZ products. Ventura Dep. at 401:9-19.
- 84. Many elements influence whether a doctor prescribes a drug, including, television and print advertisement, the PSS is merely one element. Ventura Dep. at 400:13-401:19; 406:2-408:10.
- 85. The PSS's job is to perform an advertising function by keeping the name of AZ products in the minds of health care providers. Hummel Decl. at ¶ 9.

5. Many Factors Affect Whether a Doctor Writes a Prescription

86. Many factors impact the number of prescriptions filled in the PSS's territory, including: visits by PSSs, medical education events and conventions, patients requests, television commercials, newspaper advertisements, radio advertisements, and recommendations from other physicians. Ventura Dep. at 400:13-401:19; 406:8-408:10; Johnson Dep. at 46:16-47:17 (doctors would write prescriptions for products on formulary because it was cheaper for patients).

- 87. Almost one third (32%) of Americans have talked to a doctor about a drug as a result of seeing a drug advertisement; in approximately half (44%) of the cases, the doctor wrote a prescription for the requested drug. USA Today Survey at 4, 19.
- 88. AZ's intention is for doctors to prescribe their product when it is medically necessary. Atha Dep. at 25:10-19.
- 89. The "first and foremost" reason why a doctor prescribes a particular product is if the product is safe and effective for the particular patient. Ventura Dep. at 438:2-7.
- 90. Some products do better in the market just because of the nature of the market, and not because of anything a PSS does on a sales call. Hummel Decl. at ¶ 36; DiChiara Decl. Ex. 18., AZ0025084.
- 91. Multiple PSSs will call on the same doctors to promote the same product. Ventura Dep. at 395:9-11; Hummel Decl. ¶ 35.
 - 6. The Writing of a Prescription Does Not Necessarily Result In The Filling Of The Prescription
- Patients are free to choose to decide whether they will fill a prescription 92. that a doctor has written for them. Atha Dep. at 23:21-24:1.
- 93. A significant percentage of consumers/patients do not fill their prescriptions because of cost. USA Today Survey at 3, 17.

HUMMEL IS NOT EXEMPT UNDER THE ADMINISTRATIVE H. **EXEMPTION**

Hummel did not Perform Administrative Duties 1.

- 94. All of decisions made by PSSs are solely for the promotion of Defendant's pharmaceutical products. Atha Dep. at 241:1-243:5; Johnson Dep. at 94:18-23 (all decisions made by PSSs in the field designed to help increase sales of product).
- 95. PSSs present a "promotional messag[e]" during the sales call. The promotional message is the "brand" or "core" message. Ventura Dep. at 157:4-5; 157:21-24.
- 96. Defendant considers PSSs to be engaged in "promotional activities" when they try to encourage a doctor to prescribe AZ products. Ventura Dep. at 156:17-157:24.
- 97. Hummel did not make, affect, interpret, or implement policy for AZ. Hummel Decl. at ¶ 37; Johnson Dep. at 94:24-95:4.
- 98. Hummel was not involved in planning long term or short term business objectives for AZ. *Id.*
 - 2. Hummel Did Not Exercise Discretion or Independent Judgment Concerning Matters of Significance
 - a. AstraZeneca's Strict Control of PSSs
- 99. AZ has set up a framework to instruct PSSs on what "they need to do, what they can do and what they can't do, and to keep them safe and ethical and AstraZeneca safe and ethical." Ventura Dep. at 144:15-21.
- 100. All PSSs are required to work at least 7.5 hours a day in the field calling on health care providers, exclusive of lunch and drive time to and from the first and last call. Atha Dep. at 62:6-10; DiChiara Decl., Ex. 10, AZB_C0001336-38.
- 101. If a PSS cannot be in the field for two or more hours on a particular day, the PSS must notify their district manager prior to 9 a.m. Atha Dep. at 64:5-25; DiChiara Decl., Ex. 10, AZB_C0001336-38.

- 102. PSSs are required to be in the field a set number of days per year. (In 2007, PSSs were required to be in the field 220 days per year.) DiChiara Decl., Ex. 10, AZB_C0001336-38.
- 103. Defendant requires each PSS to check their voice mail a minimum of three times per day, and a PSS *must* respond to all voice messages within 48 hours. A PSS is required to synchronize every night (including Friday). If a PSS is unable to synchronize for two consecutive days, the PSS must notify the DSM. In addition, all email messages requiring a response must be submitted within 48 hours of receipt. DiChiara Decl., Ex. 10, AZB C0001336-38.
- 104. All of the above-referenced expectations are *not suggestions*; rather, they are *requirements* of a PSSs job. Failure "to meet these expectations can and may result in discipline, up to an including termination." DiChiara Decl., Ex. 10, AZB C0001336-38.
- 105. All PSSs are expected to comply with Defendant's policies, as well as FDA laws and regulations. Atha Dep. at 106:25-107:14.
- 106. All promotional materials must be approved by AZ through an internal process referred to as eSTaR. Atha Dep. at 145-21; DiChiara Decl., Ex. 16, AZB_C0002658; DiChiara Decl., Ex. 19.
- 107. Defendant provides PSSs with promotional material to assist them in their presentations with doctors, but those materials marked for background use only cannot be shared with health care providers. Thus, even if a PSS, in exercising discretion and independent judgment, believes such material may be helpful to provide to a health care provider, Defendant prohibits a PSS from doing do. DiChiara Decl., Ex. 5, AZB_C 0000820 ("these documents are for your information only"), AZB_C0000822-0000828

("For Background Use Only. Not To Be Shared With Customers" (bottom of each page)); Ex. 6, AZB_C0000944 (and every other page thereafter) ("For education use only by AstraZeneca personnel. Not to shared with customers."); Ex. 7, AZB C0001002 ("DO NOT LEAVE BEHIND"); Ex. 8, AZB_C0001222-0001233 ("For Review Only" (on side of each page)); Ex. 9, AZB_C0001238-0001249 (same); Johnson Dep. at 40:6-24.

- PSSs cannot mark, highlight or underline promotional materials or 108. reprints. Atha Dep. at 144:2-10; DiChiara Decl., Ex. 16, AZB_C0002658; DiChiara Decl., Ex. 19; Hummel Decl. at ¶ 11.
- PSSs may only go on three access meals with a particular doctor in a given 109. year. Atha Dep. at 166:7-15; 168:2-7.
- AZ required Plaintiff to have lunches, dinners, and other programs for 110. doctors; she was given a budget for the programs that she was required to use entirely. Hummel Decl. at ¶¶29, 30; Dempsey Dep. at 39:13-40:17.
- AZ provided PSSs with a list of approved speakers from which a PSS 111. could not deviate if the PSS wanted to hold a speaker program. Dempsey Dep. at 43:9-44:1.
- During the work day, PSSs are required to check their voice mail at least 112. two times per day. DiChiara Decl. Ex. 10, AZB_C 0001336-38; Hummel Decl. at ¶ 33.
- 113. During the work day, all PSSs must check their email once a day. DiChiara Decl. Ex. 10, AZB C 0001336-38.
- In addition, Defendant dictates when PSS must respond to emails and 114. submit expense reports. DiChiara Decl. Ex. 10, AZB_C 0001336-38.

- AZ provides PSSs -- including Hummel -- a list of doctors in their 115. territory with whom PSSs should interact. Only under the guidance of their district manager, a PSS could refine this list, e.g. removing the names of deceased doctors from the list. Atha Dep. at 111:4-20; Ventura Dep. at 123:7-19; Hummel Decl. at ¶ 12; Capistrano Dep. at 288:7-289:22 (DM has final say over changes to call list).
- AZ expected Hummel to target high-prescribing or high-purchasing 116. doctors by visiting them first and more frequently than others. Hummel Decl. at ¶ 12; Johnson Dep. at 25:21-26:6 (required to call on higher ranked physicians more frequently than other doctors on call list); Dempsey Dep. at 26:3-27:2 (PSSs dictated number of times PSS to call on a particular physician and to visit higher ranked physicians more frequently).
- Even if a PSS is obtaining their sales goals, they would have, at the very 117. least, a conversation with their manager if the PSS were not calling on their assigned physicians. Dempsey Dep. at 31:16-32:7.
- PSSs may make changes to the target list of doctors, but must obtain the 118. approval of their district manager. Atha Dep. at 114:3-20; Hummel Decl. at ¶ 12.
- AZ also dictated that PSSs had to use a pen, rather then their finger, when 119. using a visual aid on a sales call. Johnson Dep. at 82:17-83:4; Dempsey Dep. at 59:1-5.

b. AstraZeneca's Strict Control of Sales Calls

120. Hummel's visits with doctors were strictly controlled by AZ. Hummel Decl. at ¶ 10.

- 121. AZ told PSSs -- including Hummel -- the message she was to convey to the doctors as well as the order in which the message should be presented. Hummel Decl. at ¶¶ 10-11.
- during their sales calls. Hummel Decl. at ¶ 11; DiChiara Decl., Ex. 5, AZB_C0000826 ("When presenting information to customers, keep it simple: 'Doctor, let me direct your attention to this chart...'"); AZB_C0000828 ("Clarify and acknowledge the feedback: 'Doctor, I am glad you asked that questions. I do have some new information I can share with you in just a minute. But before I do that, let me remind you how NEXIUM compared to PRILOSEC.""); DiChiara Decl., Ex. 19, AZ0006596-6597 ("Canned Detail-Prilosec Versus Prevacid.")
- 123. Hummel was required to stay within the scripted company message and only present information provided to her by AZ on sales calls. Hummel Decl. at \P ¶ 10-11.
- 124. PSSs are required to convey the core message and use a visual aid on each sales call. Dempsey Dep. at 58:6-12 (PSSs required to use convey core message and use visual aid).
- 125. Each and every piece of printed or written materials (e.g. clinical studies)
 PSSs including Hummel utilized or provided to doctors was pre-approved and supplied by AZ. Hummel Decl. at ¶ 10; Ventura Dep. at 103:10-105:2.
- 126. Hummel was required to stay within FDA guidelines on sales calls. Hummel Decl. at ¶ 10.

- 127. AZ's policies limit Plaintiff and other PSS's to using "access tools" with healthcare providers that have prescribing authority. It is not appropriate for a PSS to use an access tool to build goodwill or rapport. DiChiara Decl., Ex. 16, AZB C0002636-38.
- 128. Defendant strictly controls what PSSs can relay to a doctor, because if a PSS violates FDA guidelines, Defendant could be subject to severe fines. DiChiara Decl., Ex. 19 AZ0025072-25081.
- 129. Hummel and all PSSs are required to comply with FDA guidelines when addressing doctors, as they cannot discuss any off-label use for Defendant's products. Ex. 18, AZ0025076-25077.
- 130. Defendant mandates specific standards and tasks that all PSSs must perform during a "sales" call. AZB_C0038282-AZB_C0038298; Atha Dep. at 140:17-141:3; DiChiara Decl., Ex. 18, AZ0025081.
- 131. When calling on health care providers, all PSSs are required to follow AZ's standards for interacting with healthcare professionals. Atha Dep. at 134:21-135:7, 137:13-138:3.
- 132. All PSSs are required to present information about Defendant's products in accordance with the FDA prescribing information, *i.e.* the product insert. Atha Dep. at 138:23-140:15.
- 133. PSSs are required to offer the doctor a copy of the product insert. Atha Dep. at 140:11-19.
- 134. PSSs are not allowed to minimize the risks of any of Defendant's products, nor are they allowed to discuss off-label issues with health care providers. Atha Dep. at 139:19-23; 141:9-13.

- 135. If a doctor requests off-label information, the PSS is required to have a Professional Information Request sent to AZ. Atha Dep. at 141:14-19.
- 136. PSSs are required to give an objective and balanced presentation of the benefits and risks of a product. Atha Dep. at 142:10-16.
- 137. PSSs are required to point out the limits of a product's indications. Atha Dep. at 143:19-24.
- 138. PSSs cannot present statements out of context from the full prescribing information or approved promotional materials. Atha Dep. at 144:12-18.
- 139. PSS's are not allowed to present a side effect as a clinical benefit. Atha Dep. at 143:13-17.
- 140. PSS's cannot highlight or mark up promotional pieces. DiChiara Decl., Ex. 11, AZB_C0001538-44.
- 141. PSS's cannot use homemade materials on sales calls. DiChiara Decl., Ex. 11, AZB C0001538-44.
- 142. A PSS cannot compare Defendant's products with those of a competitor unless the PSS received direction from the company. DiChiara Decl., Ex. 11, AZB_C0001538-44.
- 143. AZ also strictly controls the ability of a PSS to send a facsimile to health care professional and consumers. DiChiara Decl., Ex. 12, AZB_C0004230.
- 144. After a sales call is completed, all PSSs are required to immediately enter call notes into their computer. DiChiara Decl., Ex. 10, AZB_C0001336-38.
- 145. A PSS may not engage in promotional discussions with patients. DiChiara Decl., Ex. 16, AZB_C0002650.

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- 146. If a PSS fails to follow the job requirements, the PSS can be disciplined or discharged. In fact, PSSs are closely monitored by their District Managers who regulate the activities of a PSS through telephone calls, email communications, call logs, and weekly reports. DiChiara Decl., Ex. 10, AZB_C0001336-38; Hummel Decl. at ¶ 37; Johnson Dep. at 65:25-67:4; Dempsey Dep. at 52:6-54:13, 56:17-58:5 (manager checked call notes of her PSSs on regular basis); Capistrano Dep. at 84:5-16 (95% of District Manager's job is related to supervision of PSSs), 293:13-294:1 (using call entry screen to verify activities of PSS).
- 147. Hummel's average actual time with a doctor would be less than a minute, although she would oftentimes have to wait a long period of time before seeing a doctor. Hummel Decl. at ¶ 13.
- 148. District Manager would sometimes go on ride-alongs with Hummel to judge her sales calls. Hummel Decl. at ¶ 28.
- 149. After going on a call with a doctor, PSSs are required to input information about the call into a computer. Atha Dep. at 83:20-84:2; 90:3-21; Ventura Dep. at 114:2-5; 118:9-119:21 Hummel Decl. at ¶ 126.
- by the PSS, call notes from the call, and the time and date of the entry. Atha Dep. at 90:22-91:13; Ventura Dep. at 122:1-16.
- 151. PSSs were required to visit a set number of doctors per day. Hummel Decl. ¶ 15.
- 152. PSSs were required to follow the ISS selling model on each and every sales call, even if they thought the ISS model was ineffective and they were reaching

their sales target numbers. Johnson Dep. at 89:23-90:20; Dempsey Dep. at 49:9-50:19; Capistrano Dep. at 166:8-167:2.

c. A PSS's Job Involved Mainly Basic Common Sense

- 153. PSSs did something called "Routing," which is just a fancy term for scheduling doctor visits so that PSSs do not step on each other's toes by calling on the same doctor at the same time. Johnson Dep. at 24:7-25:9, 44:13-45:2 (routing also dictated by when doctors would see pharmaceutical reps); Dempsey Dep. at 35:13-15, 36:8-18.
- 154. The patient demographics of a doctor's office also dictated what a PSS would convey on a health care provider. For example, a PSS would not promote Seroquel, a medication that treats bipolar disorder and schizophrenia, to a physician that did not have patients that suffered from those disorders. Johnson Dep. at 45:12-46:9, 56:23-57:7 (common sense to provide Nexium samples to gastroenterologists more frequently than primary care physicians because they would see more patient that needed Nexium).
- 155. Even if there were different scripted core messages that a PSS could deliver on a sales call, in many cases the message delivered was determined by the practices of the physician. Capistrano Dep. at 169:6-171:22 (if doctor already using proper dosage, no need to deliver dosing message).

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Respectfully submitted,

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